

Amendment and Response

Applicant: David Tyvoll et al.

Serial No.: 10/761,535

Filed: January 21, 2004

Docket No.: 200314393-1

Title: A METHOD OF ANALYZING BLOOD

REMARKS

The following remarks are made in response to the Office Action mailed September 28, 2007, in which claims 1-32 were rejected. It was noted in the Office Action that claim 27 contained allowable subject matter if the rejection under 35 U.S.C. 112, second paragraph was overcome. With this Response, claims 4-5, 8-11, 14-19, and 29-31 are canceled, claims 1, 6, 12, 20-25, 27-28, and 32 are amended, and new claims 33-39 are added. Claims 1-3, 6-7, 12-13, 20-28, and 32-39 are pending in the application and are presented for reconsideration and allowance.

Objection to the Abstract and to the Claims

In the Office Action, the Abstract was objected to. Applicants have amended the Abstract to recite the term “includes” instead of “comprises”, thereby obviating the objection.

In the Office Action, claims 8, 24, and 30 were objected to for informalities. Applicants have canceled claims 8 and 30 and have amended claim 24, thereby obviating the objection.

Accordingly, withdrawal of these objections is respectfully requested.

Claim Rejections under 35 U.S.C. § 112

In the Office Action, claims 12-28, and in particular claims 12, 23, and 28, were rejected under 35 U.S.C. 112, second paragraph, as being indefinite.

Claim 12 was rejected as being indefinite regarding the location of the electrode arrangement relative to the fluid flow path and the sensor. Applicants have amended claim 12 to recite that the fluid flow path includes a test chamber and that both the sensor and the electrode arrangement are disposed in the test chamber, thereby obviating the rejection.

Claim 23 was rejected for a lack of antecedent basis regarding the term “the top wall of the test chamber”. Applicants have amended claim 23 to recite “a top wall . . .”, thereby providing proper antecedent basis for this claim feature.

Claim 28 was rejected as being indefinite regarding the phrase “to measure the property of the blood sample to repel cells from the electrode arrangement.” Applicants have amended claim 28 to clarify the action of the electrode arrangement and the sensor.

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Accordingly, Applicants respectfully request withdrawal of the rejections of claims 12-28 under Section 112, second paragraph.

Claim Rejections under 35 U.S.C. § 103

In the Office Action, claims 1-26 and 28-32 were rejected under 35 U.S.C. 103(a) as being unpatentable over McAleer et al., U.S. Patent 6,241,862 (the McAleer Patent) in view of Wang et al., U.S. Patent 6,596,143 (the Wang Patent).

Applicants' independent claim 1 recites a method of analyzing blood comprising, among other things, delivering a blood sample including cells to a test chamber to directly expose the blood sample (including cells) to both a sensor and an electrode arrangement within the test chamber.

In sharp contrast, the McAleer Patent discloses a reagent/separation layer 17 that provides a barrier to prevent passage of interferents such as cells to a conductive element 16 so that no portion of the conductive element 16 (which comprises part of an electrochemical sensor) is directly exposed to the blood sample when placed in the sample application region. See, for example, Column 4, lines 38-47; Column 3, lines 8-30; Column 7, lines 4-15; Column 8, lines 1-9; and Figures 1A, 1B, and 7. Accordingly, because the conductive element 16 (as part of an electrochemical sensor) is exposed only to the screened product (e.g., glucose or "soluble electroactive species" as noted in Column 3, lines 8-30), the McAleer Patent teaches away from this claimed feature (i.e., delivering a blood sample...) of Applicants' independent claim 1.

In further contrast to Applicants' independent claim 1, the McAleer Patent discloses that the reagent/separation layer 17 that is disposed over conductive element 16 (part of an electrochemical sensor) is non-conductive. Accordingly, the McAleer Patent teaches away from the claim limitation of applying a spatially varying electric field, **via an electrode arrangement**, to the blood sample **within the test chamber**, as recited in Applicants' independent claim 1, because the McAleer Patent fails to provide an electrode arrangement that is distinct from its sensor (provided via conductive elements 16 and 14'. Accordingly, it follows that the McAleer Patent necessarily fails to teach a method in which both a sensor and an electrode arrangement (which is distinct from the sensor) are disposed within the same test chamber. To this end, the Office Action admits that the McAleer Patent fails to disclose

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that cells in the blood can be removed by applying a spatially varying electric field (via an electrode arrangement) to the blood sample.

The Wang Patent fails to cure the deficiencies of the McAleer Patent. While the Wang Patent discloses an electrode arrangement for concentrating cells, the Wang Patent does not provide a method of directly exposing a blood sample to **both** a sensor **and** an electrode arrangement with the same test chamber, as recited in Applicants' independent claim 1. Moreover, because the McAleer Patent teaches away from placing electrically conductive materials within close proximity to conductive elements 16, 14' of an electrochemical sensor (see, for example, Column 4, lines 21-32), one skilled in the art would be led away from substituting an electrode arrangement from the Wang Patent for the reagent/separation layer 17 of the McAleer Patent. Moreover, it is unclear how an electrode arrangement, such as that described in the Wang Patent, would be juxtaposed relative to conductive elements 14' and 16 of the McAleer Patent to accomplish a fluid flow from the test inlet of the substituted electrode arrangement (of the Wang Patent) to the conductive elements 16 and 14' of the electrochemical sensor of the McAleer Patent while concentrating cells via the substituted electrode arrangement. Accordingly, one skilled in the art would be led away from combining the McAleer Patent and the Wang Patent.

Neither the McAleer Patent nor the Wang Patent teach or suggest the limitation in Applicants' claim 1 of delivering a blood sample (including cells) to a test chamber to directly expose the blood sample to both a sensor and an electrode arrangement (that applies a spatially varying electric field) within the test chamber. Accordingly, Applicants respectfully submit that the combination of the McAleer Patent and the Wang Patent does not render obvious Applicants' invention defined in independent claim 1.

For at least these reasons, the McAleer Patent and the Wang Patent fail to anticipate, teach, suggest, or otherwise render obvious Applicants' independent claim 1. Accordingly, Applicants respectfully submit that independent claim 1 is allowable over the combination of the McAleer Patent and the Wang Patent. Claims 2-3 and 6-7 are believed to be allowable based on their dependency from patentably distinct independent claim 1.

In further contrast to the McAleer Patent and the Wang Patent, Applicants' dependent claim 6 further recites that sensing the property of the blood sample is performed **during**

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application of the spatially varying electric field. The McAleer Patent teaches that reagent/separation layer 17 acts a barrier to cells (and other interferents) while allowing the passage of glucose or soluble electroactive species. Accordingly, in sharp contrast to Applicants' independent claim 1 and dependent claim 6, the blood in the McAleer patent is first screened or filtered via the reagent/separation layer 17, and then afterwards, the remaining product is sensed via electrodes 14' and 16. The Wang Patent fails to cure the deficiencies of the McAleer Patent regarding this claim feature, as the Wang Patent does not provide a mechanism for sensing a property of a portion (having a depleted cell concentration) of a blood sample **during** application of a spatially varying electric field, as recited in Applicants' independent claim 6.

Applicants' independent claim 12 comprises a blood analyzer that includes a fluid flow path, a sensor, and an electrode arrangement. Among other things, claim 12 specifies that **both** a sensor and an electrode arrangement are disposed **within the test chamber**.

In sharp contrast, the McAleer Patent discloses that the reagent/separation layer 17 that is disposed over conductive element 16 (part of an electrochemical sensor) is non-conductive. Accordingly, the McAleer Patent teaches away from the claim limitations of **an electrode arrangement (configured to apply a spatially varying electric field) and a sensor within the test chamber**, as recited in Applicants' independent claim 12, because the McAleer Patent fails to provide an electrode arrangement that is distinct from its sensor (provided via conductive elements 16 and 14'). Accordingly, it follows that the McAleer Patent necessarily fails to teach a blood analyzer in which both a sensor and an electrode arrangement (which is distinct from the sensor) are disposed within the same test chamber.

In further contrast to Applicants' independent claim 12, the reagent/separation layer 17 in the McAleer Patent provides a **non-conductive** mechanism to screen out cells or other interferents and prevent direct exposure of a blood sample to its sensor (provided by conductive elements 16, 14'). Accordingly, the McAleer Patent further teaches away the claim limitation of **an electrode arrangement** configured to generate a spatially varying electric field in the test chamber to reduce a cell concentration in the portion of the blood sample adjacent to the sensor **by electrically distributing cells within the blood sample away from the sensor**, as recited in claim 12.

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The Wang Patent fails to cure the deficiencies of the McAleer Patent. While the Wang Patent discloses an electrode arrangement for concentrating cells, the Wang Patent does not provide **both** a sensor **and** an electrode arrangement disposed within a test chamber. Moreover, because the McAleer Patent teaches away from placing electrically conductive materials within close proximity to conductive elements of an electrochemical sensor (see Column 4, lines 21-32), one skilled in the art would be led away from substituting an electrode arrangement from the Wang Patent for the reagent/separation layer 17 of the McAleer Patent. Moreover, it is unclear how an electrode arrangement, such as that described in the Wang Patent, would be juxtaposed relative to conductive elements 14' and 16 of the McAleer Patent to accomplish a fluid flow from the test inlet of the electrode arrangement (of the Wang Patent) to the conductive elements 16 and 14' of the electrochemical sensor of the McAleer Patent while concentrating cells via the electrode arrangement. Accordingly, one skilled in the art would be led away from combining the McAleer Patent and the Wang Patent.

Neither the McAleer Patent nor the Wang Patent teach or suggest the limitation in Applicants' claim 12 reciting both a sensor and an electrode arrangement (configured to apply a spatially varying electric field) within a test chamber. Accordingly, Applicants respectfully submit that the combination of the McAleer Patent and the Wang Patent does not render obvious Applicants' invention defined in independent claim 12.

For at least these reasons, the McAleer Patent and the Wang Patent fail to teach, suggest, or otherwise render obvious Applicants' independent claim 12. Accordingly, Applicants respectfully submit that independent claim 12 is allowable over the combination of the McAleer Patent and the Wang Patent. Claims 13 and 20-28 are believed to be allowable based on their dependency from patentably distinct independent claim 14.

Applicants also traverse the assertion in the Office Action regarding claims 21-24 that it is obvious to vary configuration of the electrodes. As an example, Applicants note with regard to claim 23 that the McAleer Patent fails to disclose an electrode arrangement (configured to apply a spatially varying electric field) at all, and the Wang Patent fails to disclose a sensor in cooperation with its electrode arrangement. Accordingly, in addition to the reasons previously presented for the patentability of claims 1 or 12 over the combination

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of the McAleer and Wang Patents, there is no precedent or basis in those references to lead one of ordinary skill in the art to provide the sensor and the electrode arrangement **as a single unit** on one wall (the top wall) of the test chamber, as recited in Applicants' claim 23.

Applicants' independent claim 32 recites a method of testing a property of blood.

Neither the McAleer Patent nor the Wang Patent teach or suggest the features in Applicants' claim 32 including, among other things: (1) applying a first spatially varying electric field to the blood sample within the test strip and **external to a test chamber of the test strip**, to separate and exclude a first plurality of red blood cells from the blood sample to produce a modified blood sample; **AND** (2) applying a **second** spatially varying electric field to the modified blood sample **within the test chamber** to produce a relatively lower concentration of red blood cells **adjacent a sensor within the test chamber**.

First, for at least substantially the same reasons previously presented for the patentability of claims 1 and 12, it is submitted that the McAleer Patent and the Wang Patent fail to teach, suggest, or otherwise render obvious applying a (second) spatially varying electric field to a (modified) blood sample **within the test chamber** to produce a relatively lower concentration of red blood cells **adjacent a sensor within the test chamber**, as recited in Applicants' independent claim 32. In particular, as admitted in the Office Action, the McAleer Patent fails to disclose applying a spatially varying electric field. While the Wang Patent discloses an electrode arrangement for concentrating cells, the Wang Patent does not provide **both** applying a spatially varying electric field within a test chamber **and** measuring a property of the modified blood sample at the sensor within the same test chamber, as recited in Applicants' independent claim 32.

Second, for at least substantially the same reasons previously presented for the patentability of claims 1 and 12, the McAleer Patent fails to teach, suggest, or otherwise render obvious the feature of applying a first spatially varying electric field to the blood sample within the test strip and **external to a test chamber of the test strip**, to separate and exclude a first plurality of red blood cells from the blood sample to produce a modified blood sample, as recited in Applicants' claim 32. In particular, as admitted in the Office Action, the McAleer Patent fails to disclose applying a spatially varying electric field. For the reasons previously explained in association with claims 1 and 12, the Wang Patent fails to cure the

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deficiencies of the McAleer Patent and one skilled in the art would be led away from combining the McAleer Patent and the Wang Patent.

Moreover, neither the McAleer Patent nor the Wang Patent, alone or in combination, teaches applying a first spatially varying electric field on a blood sample external to a test chamber to produce a modified blood sample and then applying a second spatially varying electric field on the modified blood sample within a test chamber. Accordingly, Applicants respectfully submit that the combination of the McAleer Patent and the Wang Patent does not render obvious Applicants' invention defined in independent claim 32.

Finally, Applicants also respectfully traverse the assertion in the Office Action regarding claim 32 that one skilled in art would axiomatically be led to apply a spatially varying field at multiple times and in multiple locations. In particular, Applicants' claimed method involves a test strip as used in a self-monitoring glucose meter, which would be understood by one skilled in the art to have a limited amount of space. Accordingly, it is submitted that one cannot merely assume that one skilled in the art could or would believe they have unbounded discretion to add multiple electrode arrangements in multiple locations on a test strip.

For at least these reasons, the McAleer Patent and the Wang Patent fail to teach, suggest, or otherwise render obvious Applicants' independent claim 32. Accordingly, Applicants respectfully submit that independent claim 32 is allowable over the combination of the McAleer Patent and the Wang Patent.

In light of the above, Applicants respectfully request withdrawal of the rejection of claims 1-3, 6-7, 12-13, 20-28, and 32 under 35 U.S.C. § 103.

New Claims

Applicants present new claims 33-39.

New claim 33 presents the subject matter of "objected to" claim 27, which was indicated to be allowable if rewritten in independent form (with any base or intervening claim limitations) while overcoming the rejection under Section 112, second paragraph. Applicants' new independent claim 33 specifies that the electrode arrangement is disposed

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within the fluid flow path, thereby overcoming the Section 112 rejection and placing new claim 33 in condition for allowance.

New claims 34-39 are supported by the specification and claims as filed, and present subject matter not taught or suggested by the McAleer Patent and/or the Wang Patent. In particular, Applicants' independent claim 34 recites a blood analyzer comprising, among other things, a fluid flow path, an electrode arrangement, and a sensor.

In sharp contrast to claim 34, the McAleer Patent discloses that the reagent/separation layer 17 that is disposed over conductive element 16 (part of an electrochemical sensor) is non-conductive. Accordingly, the McAleer Patent teaches away from the claim limitations of **an electrode arrangement (configured to apply a spatially varying electric field) and a sensor**, as recited in Applicants' independent claim 34, because the McAleer Patent fails to provide an electrode arrangement that is distinct from its sensor (provided via conductive elements 16 and 14'). While the Wang Patent discloses an electrode arrangement for concentrating cells, as previously mentioned, the Wang Patent does not provide a device including both a sensor **and** an electrode arrangement. Finally, as previously explained in association with claims 1 and 12, one skilled in the art would be led away from combining the McAleer Patent and the Wang Patent.

Accordingly, Applicants respectfully submit that the combination of the McAleer Patent and the Wang Patent does not teach, suggest, or render obvious Applicants' invention defined in independent claim 34. For at least these reasons, Applicants respectfully submit that independent claim 34 is allowable over the McAleer Patent and/or the Wang Patent. Claims 35-39 are believed to be allowable based on their dependency from patentably distinct independent claim 34.

Therefore, favorable consideration and allowance of new claims 34-39 is respectfully requested.

Applicants also note that dependent claim 38 further specifies the feature of the electrode arrangement including: (1) a first portion configured to generate a traveling wave in the spatially varying electric field to deflect cells in a second direction away from a test chamber; AND (2) a second portion (separate from the first portion) configured to generate a high field region to deflect cells in the second direction away from the test chamber.

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Because the McAleer Patent fails to disclose **any** electrode arrangement (for generating fields) and the Wang Patent fails to disclose such a combination, Applicants respectfully submit that claim 38 is further patentably distinct over the McAleer Patent and the Wang Patent.

Likewise, Applicants also note that dependent claim 39 (which depends from claim 38) further specifies the feature that the first portion the electrode arrangement includes a linear electrode array and the second portion includes a gate electrode array (configured to generate the high field region recited in claim 38) disposed at a junction of the conduit portion and the test chamber. Because the McAleer Patent fails to disclose **any** electrode arrangement (for generating fields) and the Wang Patent fails to disclose such a combination, Applicants respectfully submit that claim 39 is further patentably distinct over the McAleer Patent and the Wang Patent.

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CONCLUSION

In view of the above, Applicants respectfully submit that pending claims 1-3, 6-7,12-13, 20-28, and 32-39 are in form for allowance and are not taught or suggested by the cited references. Therefore, reconsideration and withdrawal of the rejections and allowance of claims 1-3, 6-7,12-13, 20-28, and 32-39 is respectfully requested.

Applicants hereby authorize the Commissioner for Patents to charge Deposit Account No. 50-0471 in the amount of \$210.00 to cover the fees as set forth under 37 C.F.R. 1.16(h)(i).

The Examiner is invited to contact the Applicants' representative at the below-listed telephone numbers to facilitate prosecution of this application.

Any inquiry regarding this Amendment and Response should be directed to either Julia Church Dierker at Telephone No. (248) 649-9900, Facsimile No. (248) 649-9922 or Paul S. Grunzweig at Telephone No. (612) 767-2504, Facsimile No. (612) 573-2005. In addition, all correspondence should continue to be directed to the following address:

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Respectfully submitted,

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